Notice of Allowability	Application No.	Applicant(s)	
	10/825,359	GIBSON, PETER	
	Examiner	Art Unit	
	REX HOLMES	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *the communication of 1/22/10*.

2. ☒ The allowed claim(s) is/are *1,2,7-9,13,14,16-28,30,31,40-43,49,50,89-109 and 113-115*.

3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☒ All b) ☐ Some* c) ☐ None of the:
      1. ☒ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date 7/6/10; 12/10/10
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date *20101214* .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

/R. H./ Examiner, Art Unit 3762	/Niketa I. Patel/ Supervisory Patent Examiner, Art Unit 3762

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mark Kupets on 12/13/2010.

The application has been amended as follows:

1. (Previously Presented) An implantable device for mounting to a patient's bone comprising:

a housing having an abbutting face configured to prevent osseointegration of said housing with the patient's bone;

one or more components mounted in said housing; and

at least a first protuberance and a second protuberance configured to attach to the patient's bone without insertion of the first or second protuberance into the bone;

wherein said first and second protuberances extend from said housing such that a longitudinal axis of the first protuberance and a longitudinal axis of the second protuberance are at opposing angles of about 45 degrees relative to an implant axis that is substantially orthogonal with the surface of the bone forming the pocket; and

wherein the protuberance is configured to osseointegrate with the patient's bone and separate at least a portion of said outer surface of said housing from the patient's

bone when said housing is positioned within a pocket formed in the patient's bone such that the first and second protuberances abut a surface of the bone forming the pocket prior to osseointegration.

2. (Previously Presented) The implantable device of claim 1, wherein said housing abutting surface is configured to abut the patient's bone after osseointegration of the at least one protuberance.

3 -6. (Cancelled)

7. (Previously Presented) The implantable device of claim 1, wherein the implantable device is a tissue stimulating prosthesis.

8. (Previously Presented) The implantable device of claim 7, wherein said tissue stimulating prosthesis is a cochlear implant, and further wherein said one or more components comprise a stimulator unit of the cochlear implant.

9. (Previously Presented) The implantable device of claim 8, wherein a receiver antenna is operatively connected to said housing.

10-12. (Cancelled)

13. (Currently Amended) The implantable device of claim 1, wherein ~~the~~ at least one ~~osseointegrating protuberance~~ of the protuberances is configured to be permanently implanted in the patient's bone.

14. (Currently Amended) The implantable device of claim 1, wherein ~~said~~ at least one ~~protuberance~~ of the protuberances is configured to be extricated from the patient's bone subsequent to osseointegration.

15. (Cancelled)

16. (Currently Amended) The implantable device of claim 1 wherein ~~the~~ at least one ~~osseointegrating protuberance~~ of the protuberances comprises at least one loop member.

17. (Currently Amended) The implantable device of claim 1, wherein ~~the~~ at least one ~~osseointegrating protuberance~~ of the protuberances comprises at least one aperture.

18. (Currently Amended) The implantable device of claim 1, wherein ~~the~~ at least one ~~osseointegrating protuberance~~ of the protuberances comprises at least one substantially smooth shaft.

19. (Previously Presented) The implantable device of claim 18, wherein the at least one substantially smooth shaft comprises a plurality of substantially smooth shafts each having a longitudinal axis, wherein the longitudinal axes of the shafts lie in different planes.

20. (Currently Amended) The implantable device of claim 22, wherein each of said ~~at least one protuberance~~ protuberances comprises at least one threaded shaft.

21. (Currently Amended) The implantable device of claim 1, further comprising: at least one elongate flange extending from said housing in a direction substantially parallel with a surface of the bone when the device is in an implant orientation, and wherein each of said ~~at least one osseointegrating protuberance~~ protuberances is operationally disposed on one of said at least one flange so as to be laterally offset from said housing.

22. (Currently Amended) The implantable device of claim 21, wherein each of said ~~at least one laterally offset protuberance~~ of the protuberances is configured to be

manipulated to extricate said protuberance from the bone subsequent to osseointegration.

23. (Currently Amended) The implantable device of claim 20, wherein each of said ~~protuberance~~ protuberances is a screw and wherein said threaded shaft is a part of said screw.

24. (Previously Presented) The implantable device of claim 21, wherein said at least one elongate flange is configured to prevent osseointegration.

25. (Currently Amended) The implantable device of claim 1, wherein ~~the~~ at least one ~~osseointegrating protuberance~~ of the protuberances comprises at least one fastening member mounted to a support.

26. (Previously Presented) The implantable device of claim 25, wherein the at least one fastening member comprises one or more of the group consisting of:

a screw;

a clip; and

a nail.

27. (Currently Amended) The implantable device of claim 1, wherein said at least one ~~protuberance~~ of the protuberances is formed of or coated with one of either titanium or titanium alloy.

28. (Currently Amended) The implantable device of claim 1, wherein said at least one ~~protuberance~~ of the protuberances comprises a protuberance surface treatment configured to encourage osseointegration.

29. (Cancelled)

30. (Previously Presented) The implantable device of claim 1, wherein said housing abutting surface is formed of a material coated with a biocompatible silicone.

31. (Previously Presented) The implantable device of claim 1, wherein said housing abutting surface is formed from at least one of a biocompatible metallic, ceramic and polymeric material.

32-39. (Cancelled)

40. (Currently Amended) The ~~prosthesis~~ implantable device of claim ~~32~~ 108, wherein the at least one ~~osseointegrating protuberance~~ of the protuberances comprises at least one loop member.

41. (Currently Amended) The ~~prosthesis~~ implantable device of claim ~~32~~ 108, wherein the at least one ~~osseointegrating protuberance~~ of the protuberances comprises at least one aperture.

42. (Currently Amended) The ~~prosthesis~~ implantable device of claim ~~32~~ 108, wherein the at least one ~~osseointegrating protuberance~~ of the protuberances comprises at least one substantially smooth shaft.

43. (Currently Amended) The ~~prosthesis~~ implantable device of claim 42, wherein the at least one substantially smooth shaft comprises a plurality of substantially smooth shafts each having a longitudinal axis, wherein the longitudinal axes of the shafts lie in different planes.

44-48. (Cancelled)

49. (Currently Amended) The ~~prosthesis~~ implantable device of claim ~~32~~ 108, wherein the at least one ~~osseointegrating protuberance~~ of the protuberances comprises at least one fastening member mounted to a support.

50. (Currently Amended) The ~~prosthesis~~ implantable device of claim 49, wherein the at least one fastening member comprises one or more of the group consisting of:

a screw;

a clip; and

a nail.

51-88. (Cancelled)

89. (Previously Presented) The implantable device of claim 1, wherein the implantable device is a tissue stimulating prosthesis.

90. (Previously Presented) The implantable device of claim 89, wherein said housing and said one or more components comprise a stimulator unit of a cochlear implant.

91. (Currently Amended) The implantable device of claim 1, wherein each of ~~said at least one protuberance~~ protuberances comprises at least one feature that facilitates osseointegration.

92. (Currently Amended) The implantable device of claim 1, wherein each of ~~said at least one protuberance~~ protuberances is configured to prevent substantial relative lateral movement between the implantable device and the patient's bone.

93. (Currently Amended) A method for implanting an implantable device having a housing with an abutting surface configured to prevent osseointegration of the housing

with a patient's bone and at least one osseointegrating protuberance extending from the housing, the method comprising:

forming a pocket on the patient's bone to receive the housing;

positioning the housing in said pocket such that the at least one protuberance is in direct contact with a surface of the patient's bone forming the pocket; and

allowing osseointegration of the at least one protuberance to occur without insertion of the at least one protuberance into the surface of the patient's bone forming the pocket,

whereby when the at least one protuberance is osseointegrated the abutting surface of the housing is not osseointegrated.

94. (Previously Presented) The method of claim 93, wherein the at least one protuberance comprises at least two protuberances, the method further comprising: positioning said at least two protuberances adjacent surfaces of the patient's bone.

95. (Previously Presented) The method of claim 94, wherein the at least two protuberances each have a longitudinal axis that lies in a same imaginary plane at opposing angles relative to an implant axis that is substantially orthogonal with the housing abutting surface, the method further comprising: positioning said at least two protuberances adjacent to the patient's bone such that the implant axis is substantially orthogonal to the patient's bone and such that at least a portion of the housing abutting surface is spaced from patient's bone before osseointegration occurs.

96. (Previously Presented) The method of claim 95, wherein the opposing angles between the longitudinal axes of the protuberances and the implant axis are each approximately between 5 and 85 degrees to provide a permanent implantation.

97. (Previously Presented) The method of claim 93, wherein the implantable device is a tissue stimulating prosthesis.

98. (Previously Presented) The method of claim 97, wherein the tissue stimulating prosthesis is a cochlear implant.

99. (Previously Presented) The method of claim 93, wherein forming a pocket comprises:

forming said pocket in the patient's bone, wherein the patient's bone is selected from the group consisting of a periosteum, skull, and a mastoid process.

100. (Previously Presented) The method of claim 93, further comprising:

extricating said at least one protuberance from the bone subsequent to osseointegration of the protuberance.

101. (Previously Presented) The method of claim 93, wherein the implantable device further comprises a flange extending from the housing in a direction substantially parallel with a surface of the bone when the device is in an implant orientation, wherein one or more of the at least one protuberance is disposed on the flange such that the one or more protuberances are laterally offset from the housing.

102. (Previously Presented) The method of claim 101, further comprising:

manipulating, subsequent to osseointegration, the one or more laterally-offset protuberances to extricate the one or more protuberances from the bone.

103. (Previously Presented) The method of claim 102, wherein the at least one elongate flange is configured to prevent osseointegration.

104. (Previously Presented) The method of claim 93, wherein the at least one protuberance is formed o f or coated with one of either titanium or titanium alloy.

105. (Previously Presented) The method of claim 93, wherein the at least one protuberance comprises a protuberance surface treatment configured to encourage osseointegration.

106. (Previously Presented) The method of claim 93, wherein the housing abutting surface is formed of a material coated with a biocompatible silicone.

107. (Previously Presented) The method of claim 93, wherein the housing abutting surface is formed from at least one of a biocompatible metallic, ceramic and polymeric material.

108. (Previously Presented) An implantable device comprising:

a housing to be secured to a patient's bone, said housing having an abutting surface configured to prevent osseointegration of said housing with the patient's bone;

one or more components mounted in said housing; and

at least a first and a second osseointegrating protuberance, each extending from said housing, wherein said first and second osseointegrating protuberance are configured to be placed in direct contact with a surface of the patient's bone but not within the patient's bone and further configured to gradually sink into the patient's bone during osseointegration of said protuberance; and

wherein said first and second protuberances extend from said housing such that a longitudinal axis of the first protuberance and a longitudinal axis of the second protuberance are at opposing angles of about 45 degrees relative to an implant axis that is substantially orthogonal with the surface of the patient's bone.

109. (Previously Presented) The implantable device of claim 108, wherein said housing abutting surface is configured to abut the patient's bone after osseointegration of ~~the~~ at least one ~~osseointegrating protuberance~~ of the protuberances.

110 -112. (Cancelled)

113. (Previously Presented) The implantable device of claim 108, wherein the implantable device is a tissue stimulating prosthesis.

114. (Previously Presented) The implantable device of claim 108, wherein ~~said~~ at least one ~~protuberance~~ of the protuberances is configured to be extricated from the patient's bone subsequent to osseointegration.

115. (Previously Presented) The implantable device of claim 108, further comprising: at least one elongate flange extending from said housing in a direction substantially parallel with a surface of the patient's bone when the device is in an implant orientation, and wherein each of said ~~at least one osseointegrating protuberance~~ protuberances is operationally disposed on one of said at least one flange so as to be laterally offset from said housing.

116 - 118. (Cancelled)

Election/Restrictions

2. Claims 1,2,7-9,14,20-28,30,31, 89-109 and 113-115 are directed to an allowable product. Pursuant to the procedures set forth in MPEP § 821.04(B), claims 13, 16-19, 25-26, 40-43, 49-50, directed to the process of making or using an allowable product, previously withdrawn from consideration as a result of a restriction requirement, are hereby rejoined and fully examined for patentability under 37 CFR 1.104.

Because all claims previously withdrawn from consideration under 37 CFR 1.142 have been rejoined, **the restriction requirement as set forth in the Office action mailed on 8/15/06 is hereby withdrawn**. In view of the withdrawal of the restriction requirement as to the rejoined inventions, applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

3. The following is a statement of reasons for the indication of allowable subject matter: The subject matter for the independent claims could not be found or was not suggested in the prior art. The subject matter not found was the first and second protuberances at opposing angles of about 45 degrees relative to an implant axis that is

substantially orthogonal with the surface of the bone forming the packet in combination with the other limitations of the claim.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled “Comments on Statement of Reasons for Allowance.”

Any inquiry concerning this communication or earlier communications from the examiner should be directed to REX HOLMES whose telephone number is (571)272-8827. The examiner can normally be reached on M-F 9:00 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Niketa Patel can be reached on (571) 272-4156. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. H./
Examiner, Art Unit 3762
/Niketa I. Patel/

Supervisory Patent Examiner, Art Unit 3762